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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/677,956	10/01/2003	Suzanne Zebedee	323-100US D	9260

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EXAMINER	
LUCAS, ZACHARIAH	
ART UNIT	**PAPER NUMBER**
1648	

DATE MAILED: 03/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/677,956	ZEBEDEE ET AL.	
	Examiner	Art Unit	
	Zachariah Lucas	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 November 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *102-111* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *102-111* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. A prior requirement for restriction was mailed on February 22, 2006. requiring restriction among the inventions described by previously pending claims 77-101. However, prior to the mailing of that requirement, the Applicant submitted a new preliminary amendment canceling claims 77-101, and submitting new claims 102-111. In view of the amendment, and the prior requirement for restriction is withdrawn in favor of the requirement below.

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 102-105, and 109-111, drawn to assays for detecting anti-HCV (NANBV) capsid antibodies in a sample, and a kit comprising an HCV capsid antigen, classified in class 435, subclass 7.1.

II. Claims 106, and 109-111, drawn to a method for the preparation of a diagnostic composition comprising the use of an HCV capsid antigen, classified in class 530, subclass 350.

III. Claims 107-111, drawn to a kit comprising an HCV capsid antigen, classified in class 424, subclass 189.1.

The inventions are distinct, each from the other because of the following reasons:

3. The invention of Group III is related as product and processes of use with the inventions of Groups I and II. The inventions can be shown to be distinct if either or both of the following

can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the claimed products may be used in method for the detection of antibodies as claimed, or in methods for inducing an immune response. The products are therefore distinct from the claimed methods of use.

4. The inventions of Groups I and II are directed to related methods. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, the claimed methods have different functions and modes of operation. In Group I, the method is directed to the detection of an antibody. In Group II, the method is directed to the making of a composition. Thus, the methods perform different functions, and have different modes of operation. The methods are therefore distinct one from the other.

Species Election

5. This application contains claims directed to the following patentably distinct species of the claimed invention:

If Group I is elected above, the Applicant is additionally required to elect one of each from species (A)-(C), and species (1)-(5).

Species (A)-(C) represent the elected invention wherein the specific binding agent is (A) protein A, (B) and IgG antibody, or (C) and IgM antibody.

Species (1)-(3) represent the elected invention wherein the label is (1) a lanthanide chelate, (2) biotin, (3) an enzyme, (4) a radioactive isotope, or (5) a fluorescent moiety. Claims 102 and 103 are considered generic.

If any of Groups I-III are elected above, the Applicant is additionally required to elect one of the following species of the capsid antigen:

(i) embodiments wherein the antigen comprises residues 1-20 of the HCV capsid protein,

(ii) embodiments wherein the antigen comprises residues 21-40 of the HCV capsid protein,

(iii) embodiments wherein the antigen comprises residues 69-102 of the HCV capsid protein

Claims 102, 106, and 107 are considered generic in Groups I, II, and III, respectively. Also, the species comprising residues 1-120 is considered to be generic to each of the species (i)-(iii). The species comprising residues 1-74 is considered generic to species (i) and (ii).

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Examiner's Notes

6. In review the submitted claims, the following problems were noted which would result in the object of, or rejection of the claims if a Group comprising the relevant claims was elected for examination.

Claim 106 is an improper use claim, not permitted in U.S. patent practice. For the purposes of this action, the claim is treated a method claim. It is suggested that the claim be amended to read on a method for the preparation of a diagnostic composition comprising at least the step of providing an NANBV capsid antigen.

Claims 107-111 relate to inventions comprising an NANBV (HCV) capsid antigen according to SEQ ID NO: 1. However, SEQ ID NO: 1 is a polynucleotide sequence encoding an HIV antigen, not a protein sequence from the NANB virus. For the purpose

of this restriction requirement, the reference to the sequence identification number is ignored, and is treated as a reference to the positions in the NANBV capsid protein.

It is suggested that the Applicant intended to refer to the antigen of SEQ ID NO: 8.

Claims 10-111 are each improper multiple dependent claims as they each depend from at least one other multiple dependent claim. In U.S. Patent practice, a multiple dependent claim may not depend from another such claim.

Conclusion

7. Because these inventions are distinct for the reasons given above, and because the literature and sequence searches required for any one of the groups is not required for the others, restriction for examination purposes as indicated is proper.

8. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

9. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachariah Lucas whose telephone number is 571-272-0905. The examiner can normally be reached on Monday-Friday, 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Z. Lucas
Patent Examiner